Amendment of Claims

Claims 1-9 (Cancelled)

Claims 10-12 (Previously Cancelled)

Claims 13-49 (Cancelled)

50. (Previously presented) A pharmaceutical composition for treating autoimmune disease comprising an agent selected from the group consisting of Etx, EtxB, mutants of Etx or EtxB, derivatives of Etx or EtxB, and antibody agent having GM1 binding activity; wherein said agent is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease; and wherein said agent has an effect on GM-1 mediated intracellular signaling events.

51. (Previously presented) A composition according to claim 50 wherein said agent is selected from the group consisting of Etx, EtxB, and antibodies capable of binding GM1.

52. (Previously presented) A composition according to claim 50 wherein said agent is EtxB.

53. (Previously presented) A pharmaceutical composition according to claim 50 wherein said pharmaceutical composition further comprises an effective amount of antigen.

54. (Amended) The pharmaceutical composition according to claim ~~52~~ 53 wherein said antigen further comprises a self or cross reacting antigen.

55. (Previously presented) A composition according to claim 50 wherein said autoimmune disease is already in progress.

56. (Previously presented) A composition according to claim 50 wherein the pharmaceutical composition is for the prevention of the onset of a disease.

57. (Amended) A composition according to claim ~~52~~ 53 wherein the antigen is insulin.

58. (Amended) A composition according to claim ~~52~~ 53 wherein the antigen is GAD.

59. (Amended) A composition according to claim ~~52~~ 53 wherein the antigen is an islet associated antigen.

60. (Previously presented) A pharmaceutical composition according to claim 50, wherein said pharmaceutical composition is in the form of a lotion, a solution, a cream, an ointment, a dusting powder, a skin-patch, a nasal spray, an aerosol, an injectable, a pessary, a suppository, a tablet, or a capsule.

61. (Previously presented) A pharmaceutical composition according to claim 50 further comprising at least one preservative.

62. (Previously presented) A pharmaceutical composition according to claim 50, wherein said composition is adapted for systemic administration.

63. (Previously presented) A pharmaceutical composition according to claim 50, wherein said composition is adapted for oral, injection, topical, inhalation, parenteral, mucosal, intramuscular, intravenous, subcutaneous, intraocular, or transdermal administration.

64. (Previously presented) A pharmaceutical composition according to claim 51, wherein said composition is adapted for oral, injection, topical, inhalation, parenteral, mucosal, intramuscular, intravenous, subcutaneous, intraocular, or transdermal administration.

65. (Previously presented) A pharmaceutical composition for treating autoimmune disease selected from the group consisting of diabetes, arthritis and multiple sclerosis comprising an agent selected from the group consisting of Etx, EtxB, mutants of Etx or EtxB, derivatives of Etx or EtxB, and antibody agent having GM1 binding; wherein said agent is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease; wherein said agent has an effect on GM-1 mediated intracellular signaling events; and wherein if said agent is for coadministration with an antigen, then the agent and the antigen are not so linked to form a single active agent.

66. (Previously presented) A pharmaceutical composition for treating diabetes comprising an agent selected from the group consisting of Etx, EtxB, mutants of Etx or EtxB, derivatives of Etx or EtxB, and antibody agent having GM1 binding activity; wherein said agent is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease; wherein said agent has an effect on GM-1 mediated intracellular signaling events; and wherein if said agent is for coadministration with an antigen, then the agent and the antigen are not so linked to form a single active agent.

67. (Previously presented) A pharmaceutical composition for treating autoimmune disease comprising an agent selected from the group consisting of Etx, EtxB, mutants of Etx or EtxB, derivatives of Etx or EtxB, and antibody agent having GM1 binding activity; wherein said agent is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease; wherein said agent has an effect on GM-1 mediated intracellular signaling events; and wherein if said agent is for coadministra-

tion with an antigen, then the agent and the antigen are not so linked to form a single active agent.

68. (Previously presented) A pharmaceutical composition for treating autoimmune disease comprising an agent selected from the group consisting of Etx, EtxB, mutants of Etx or EtxB, derivatives of Etx or EtxB, and antibody agent having GM1 binding activity; wherein said agent is capable of modulating a ganglioside associated activity in an amount effective to treat autoimmune disease; wherein said agent has an effect on GM-1 mediated intracellular signaling events; and wherein the pharmaceutical composition further comprises an antigen, wherein the agent and the antigen are not so linked to form a single active agent.